UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Mylan N.V. Securities Litigation	No. 16-cv-07926 (JPO)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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TABLE OF ABBREVIATIONS

201_ 10-K	Mylan Inc. or Mylan N.V.'s Annual Report on Form 10-K to the SEC filed in the year in question
2016 8-K	Mylan N.V.'s Current Report on Form 8-K to the SEC, dated October 7, 2016
ANDA	Abbreviated New Drug Application
CMS	Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Agency
Complaint	Amended Class Action Complaint, dated March 20, 2017 [Dkt. #39]
Company	Mylan N.V. and/or Mylan Inc.
Defendants	Mylan N.V., Mylan Inc., Heather Bresch, Robert J. Coury, Paul B. Campbell, Kenneth S. Parks and John D. Sheehan
Dey	Dey L.P.
DOJ	U.S. Department of Justice
EpiPen	EpiPen Auto-Injector® and EpiPen Jr. Auto-Injector®
Ex. __	Exhibit __ to the Accompanying Declaration of Stefan H. Atkinson, dated May 30, 2017
FDA	U.S. Food and Drug Administration
Heritage	Heritage Pharmaceuticals Inc.
Individual Defendants	Heather Bresch, Robert J. Coury, Paul B. Campbell, Kenneth S. Parks and John D. Sheehan
Mayne	Mayne Pharma (USA), Inc.
MDRP	Medicaid Drug Rebate Program
Mylan	Mylan N.V. and/or Mylan Inc.
NDA	New Drug Application
Plaintiffs	Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd., and Dan Kleinerman
PSLRA	Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4
SOX	Sarbanes-Oxley Act, 15 U.S.C. § 7201
SEC	U.S. Securities and Exchange Commission
Section 10(b)	Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5
Section 20(a)	Securities Exchange Act, 15 U.S.C. § 78t(a)
TASE	Tel Aviv Stock Exchange
Teva	Teva Pharmaceutical Industries Ltd.

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PRELIMINARY STATEMENT

Despite having now had two bites at the apple, Plaintiffs have failed to plead any securities law violations. Instead, they have shoehorned nearly a dozen unproven allegations of regulatory and antitrust wrongdoing by Mylan into an omnibus securities complaint—hoping to capitalize on other proceedings that have nothing at all to do with Mylan's disclosures. But these are not securities issues. They are, if anything, regulatory and antitrust issues that other courts and agencies are considering in due course, under applicable, non-securities laws.

Plaintiffs' lead allegation is that Defendants "knowingly misclassified" EpiPen (thereby taking advantage of a lower rebate payment to Medicaid), and then defrauded investors by failing to disclose the alleged misclassification. But this claim fails. CMS, the agency responsible for administering the MDRP, expressly determined—in writing—that it was "entirely fitting and proper" to classify EpiPen as Mylan did. For this reason and others, Plaintiffs' theory that Defendants had a duty to disclose an alleged "misclassification" is a non-starter. And Plaintiffs' claim that Defendants had to disclose their other alleged "wrongdoing"—consisting entirely of unproven allegations of anticompetitive conduct—is equally meritless, as it relies only on conclusory allegations that fail to plead any wrongdoing requiring disclosure.

Plaintiffs' efforts to plead scienter are also lacking, for many of the same reasons. To survive, the Complaint must plead facts that give rise to a "strong inference" of scienter that is at least as compelling as any opposing inference. But in light of CMS' written guidance concerning EpiPen's classification (which Plaintiffs ignore), and in light of Plaintiffs' otherwise deficient allegations concerning the DOJ's investigation of Mylan's appropriate classification and concerning Mylan's supposed antitrust violations, Plaintiffs clearly fail to plead with particularity—as they must—that Defendants acted with intent to defraud Mylan investors or acted in a way that was an extreme departure from the standard of care.

Finally, even if Plaintiffs had adequately pleaded a securities claim (and they have not), the vast majority of their alleged losses would have to be dismissed for a lack of loss causation. That is because those alleged losses are not, among other deficiencies, connected to anything Defendants are alleged to have concealed.

For these reasons and others, described more fully below, Defendants respectfully request that the Court dismiss the Complaint in its entirety, and with prejudice.

STATEMENT OF FACTS

Mylan develops, licenses, manufactures, markets and distributes brand-name and generic pharmaceuticals worldwide. (Compl. ¶ 2.) These products include EpiPen, a "device for injecting a measured dose of epinephrine by means of auto-injector technology to treat severe allergic reactions" (*id*. ¶ 26), as well as hundreds of generic drugs (*see id*. ¶ 2).

EpiPen Classification Allegations. The MDRP requires drug manufacturers to pay rebates to Medicaid based on one of two alternative formulas. (*Id*. ¶¶ 5, 76-77.) The formula that results in a higher rebate applies to "single source drugs" and "innovator multiple source drugs" (collectively, "innovator" drugs); the formula that results in a lower rebate applies to all "other drugs" (collectively, "noninnovator" drugs). 42 U.S.C. § 1396r-8(c)(1), (2), (3). To qualify as an innovator, a drug must be approved by the FDA under an "*original* new drug application" (or "*original* NDA"). *Id.* § 1396r-8(k)(7)(A)(ii), (iv) (emphasis added). Although "original NDA" is the pivotal term in the MDRP drug-category regime, the term is not defined in the Medicaid rebate statute, and CMS expressly has recognized that the term has "created ambiguity" and is in need of clarification.[1]

[1] CMS FY2016 Congressional Justification of Estimates for Appropriations Committees to Congress at 159, *available at* https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2016-CJ-Final.pdf; *see also, e.g.,* 81 Fed. Reg. 5170-01, 5193 (Feb. 1, 2016) (final rule "is designed to clarify" definition of "original NDA");

Against this backdrop, Dey (which marketed EpiPen until Mylan acquired the company in 2007 (Compl. ¶ 57)), sought guidance from CMS about how to classify EpiPen. CMS responded that "*it is entirely fitting and proper for you to report [EpiPen] to the Drug Rebate Program with a Drug Category of 'N' (Non-Innovator, Multiple Source) and be subject to the lowest rebate amount*".[2] Based on this guidance,[3] Dey reported the product to CMS as a noninnovator, and Mylan continued reporting it as such after it acquired Dey. (Compl. ¶ 8.)

In November 2014, the DOJ issued a subpoena to Mylan, thereby commencing an investigation into whether EpiPen was "properly classified with . . . [CMS] as a non-innovator

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77 Fed. Reg. 5318, 5323 (Feb. 2, 2012). The Court may consider legislative materials such as these in connection with this motion. *See, e.g.*, *Ass'n of Home Appliance Mfrs. v. City of N.Y.*, 36 F. Supp. 3d 366, 371 (S.D.N.Y. 2014) ("Judicial notice may be taken of material that is a matter of public record . . . , such as legislative history." (*citing, e.g.*, *Blue Tree Hotels Inv. (Can.), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004))); *see also Kramer v. Time Warner Inc.*, 937 F.2d 767, 773 (2d Cir. 1991) ("In considering a motion to dismiss . . . , a district court must limit itself to facts stated in the complaint or in documents attached to the complaint as exhibits or incorporated in the complaint by reference. Of course, it may also consider matters of which judicial notice may be taken under Fed. R. Evid. 201.").

[2] Inside Health Policy, *CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset* (Sept. 2, 2016) (Ex. 3) (quoting 1997 letter from CMS (emphasis added)). This article is incorporated into the Complaint by reference (*see* Compl. ¶¶ 18, 308 & n.54), and, in fact, serves as a basis for Plaintiffs' claimed losses (*id*. ¶ 308). Furthermore, Mylan disclosed in its 2016 8-K—another document relied on by Plaintiffs (*see id.* ¶¶ 85, 311 & n.57)—that "EpiPen Auto-Injector has been classified with CMS as a non-innovator drug since before Mylan acquired the product in 2007 *based on longstanding written guidance from the federal government*." (Emphasis added.) The Court may consider CMS' guidance on this motion. *See, e.g.*, *Kramer*, 937 F.2d at 773; *Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016) (holding that, on a motion to dismiss a securities action, a court may consider the complaint, "any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff upon which it relied in bringing the suit").

[3] Similarly, in October 2008, the U.S. Department of Veterans Affairs determined in writing that EpiPen's NDA was not an "original NDA" and that EpiPen was therefore not a "covered drug" under the Veterans Health Care Act. That statute defines "covered drug" to include all drugs that are innovator drugs under the Medicaid rebate statute. *See* 38 U.S.C. § 8126(h)(2).

drug" (the "DOJ Investigation"). (*Id.* ¶ 72.) In October 2016, Mylan announced that it had agreed to settle the DOJ Investigation, but not to admit any wrongdoing. (*Id.* ¶ 85.) Plaintiffs allege that Mylan intentionally misclassified EpiPen so as to pay the lower rebate (*id.* ¶ 4)—even though it was simply following CMS' guidance as to the appropriate classification—and that this supposed misconduct (as well as the DOJ Investigation) had to have been disclosed (*id.* ¶¶ 80-81).

Antitrust Allegations. Next, Plaintiffs allege that Mylan should have disclosed other unproven, conclusory allegations, namely that it was committing antitrust violations by way of (1) Mylan's contracts with schools for EpiPen; (2) an alleged "pay-for-delay" settlement between Teva and others regarding EpiPen; (3) alleged market-allocation of a generic drug, doxycycline; and (4) alleged price-fixing with respect to five other generic drugs. (*Id.* ¶¶ 12-13.) Plaintiffs derive these allegations from reports of government investigations or allegations in civil lawsuits—but, again, none of it has been proven. (*Id.* ¶¶ 99, 113; 2017 10-K (Ex. 1) at 172-73.)

ARGUMENT

Plaintiffs attempt in their Complaint to plead a claim under Section 10(b) (Compl. ¶¶ 352-57 (Count I)), as well as two other claims predicated on that primary claim—under Section 20(a) (*id.* ¶¶ 358-62 (Count II)) and Israeli law (*id.* ¶¶ 363-69 (Count III)). All fail.

To successfully plead securities fraud under Section 10(b), Plaintiffs must allege—with particularity[4]—"(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security;

[4] The PSLRA requires that the Complaint "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading". 15 U.S.C. § 78u-4(b)(1). The Complaint must also "state with particularity"—"with respect to each act or omission alleged to violate" the federal securities laws—"facts giving rise to a strong inference that the defendant acted with the required state of mind". *Id.* § 78u-4(b)(2)(A). Similarly, Rule 9(b) requires Plaintiffs to "state with particularity the circumstances constituting fraud".

(4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation". *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157 (2008); *Ashland Inc. v. Morgan Stanley & Co.*, 652 F.3d 333, 337 (2d Cir. 2011). The Complaint fails to meet these rigorous standards, because Plaintiffs fail to plead that Mylan had to disclose the alleged, unadjudicated wrongdoing (*see* Section I.A), and because Plaintiffs fail sufficiently to plead that any of the statements they challenge were made with scienter (*see* Section I.B). Thus, Plaintiffs' Section 10(b) claim should be dismissed. Importantly, even if the Court decides to permit some portion of Plaintiffs' Section 10(b) claim to proceed, most of Plaintiffs' alleged losses should be dismissed for a failure to plead loss causation, because, among other reasons, those losses have nothing to do with the omissions Plaintiffs allege. (*See* Section I.C.)

Without a predicate violation of Section 10(b), Plaintiffs' Section 20(a) claim should also be dismissed. (*See* Section II.) For this reason and others—including jurisdictional and forum-related deficiencies—Plaintiffs' Israeli law claim should be dismissed too. (*See* Section III.)

I. PLAINTIFFS FAIL TO STATE A CLAIM FOR VIOLATION OF SECTION 10(b).

A. Defendants Were Not Required To Disclose the Alleged, Unadjudicated Wrongdoing.

Plaintiffs ask this Court to find Defendants liable for their not having disclosed the supposed misconduct that Plaintiffs allege. But Plaintiffs fail sufficiently to plead that the misconduct actually occurred (*see* Section I.A.i), or that Defendants had any duty to disclose it (*see* Section I.A.ii). For these reasons—*either* of which is sufficient to dismiss Plaintiffs' claims concerning alleged wrongdoing—Plaintiffs' allegations fail to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *See Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 578 (S.D.N.Y. 2016); *In re Axis Capital Holdings Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 585 (S.D.N.Y. 2006).

i. Plaintiffs Fail To Allege Any Underlying Misconduct.

As this Court has recognized, there is precedent in the Second Circuit requiring plaintiffs in PSLRA cases like this to plead with particularity that the underlying misconduct that they claim should have been disclosed actually took place.[5] While Defendants submit that particularity is required, Plaintiffs fail even under the lower, plausibility, standard.

EpiPen Classification (Compl. ¶¶ 33-77). Plaintiffs contend that Defendants had to disclose that they "knowingly misclassified" EpiPen under the MDRP. (*Id.* ¶¶ 4-5.) But Plaintiffs' entire argument is based on their claim that MDRP classification is "straightforward" and "simple"—specifically, that there exists a "bright-line rule" that "all drugs that are approved under NDAs" are innovators. (*Id.* ¶¶ 6-10, 44, 47; *see also* 2016 10-K (Ex. 4) at 10.) But nowhere in the Complaint do Plaintiffs ever admit the critical fact that appears on the face of the very documents on which they rely—that Mylan classified EpiPen based on longstanding advice from CMS that a "noninnovator" classification for the drug was *correct*. (*See* Statement of Facts.) Simply, Mylan could not have "knowingly misclassified" EpiPen when CMS approved the classification. Therefore, Plaintiffs' supposed "bright-line rule" that "all drugs that are approved under NDAs" must be classified as innovators, is inconsistent with CMS' own guidance regarding EpiPen. The claim should be dismissed on this ground alone.

In addition, Plaintiffs' supposed "bright-line rule" cannot be reconciled with the controlling statute, and has been rejected by CMS regulations (and, of course, by CMS itself, applying its own rule). As noted, under the Medicaid statute, only drugs approved under an

[5] *See Menaldi*, 164 F. Supp. 3d at 578 (citing *Axis*, 456 F. Supp. 2d at 585; *In re Yukos Oil Co. Sec. Litig.*, No. 04 CIV. 5243 (WHP), 2006 WL 3026024, at *14 (S.D.N.Y. Oct. 25, 2006); *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 632 (S.D.N.Y. 2005)); *see also Bd. of Trs. of City of Ft. Lauderdale Gen. Emps.' Ret. Sys. v. Mechel OAO*, 811 F. Supp. 2d 853, 879 (S.D.N.Y. 2011), *aff'd sub nom. Frederick v. Mechel OAO*, 475 F. App'x 353 (2d Cir. 2012); *In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 354 (S.D.N.Y. 2008).

"original NDA" qualify as innovators. *See* 42 U.S.C. §§ 1396r-8(k)(7)(ii), (iv). Plaintiffs' "bright-line rule" would give no meaning to the word "original" and would effectively read it out of the statute, violating the "well-settled principle[] of statutory construction [that] language should be read to give effect to each of its terms". *Huarcaya v. Mukasey*, 550 F.3d 224, 229 (2d Cir. 2008). Moreover, CMS expressly recognized in a 2016 Final Rule, issued after notice-and-comment rulemaking, that some NDAs are not "original". *See* 81 Fed. Reg. at 5191. Instead, according to CMS, the determination of whether an NDA is "original" depends on "the unique facts and circumstances" of a drug's approval, and certain NDAs—including "certain types of literature-based 505(b)(2) NDA approvals" and "paper NDA[s]"—are more likely than others to be *non*-original. *Id.*

Against this complex regulatory framework, Plaintiffs have not pleaded, and could not plead, that Defendants "knowingly misclassified" EpiPen under the MDRP. (Compl. ¶¶ 4-5.) Plaintiffs make only one factual allegation about EpiPen's approval—that it was approved under an NDA. But they say nothing about the specific approval route (*e.g.*, 505(b)(2)) under which the FDA approved the application. Nor do they allege any of the "unique facts and circumstances" surrounding EpiPen's approval. Plaintiffs thus fail to allege facts sufficient to establish that EpiPen's NDA was "original" or that (contrary to CMS' written determination) it was not "entirely fitting and proper" to classify EpiPen as a noninnovator.[6] Plaintiffs' allegation

[6] The Complaint also misstates the law by asserting that drugs without therapeutic equivalents must be classified as innovators. (*See id.* ¶¶ 52, 61.) Under the statute, only "single source" and "innovator multiple source" drugs—*i.e.*, drugs with "original NDAs"—are subject to the innovator rebate formula. *See* 42 U.S.C. § 1396r-8(c)(1), (2). The lower formula applies to all drugs "other than single source drugs and innovator multiple source drugs". *Id.* § 1396r-8(c)(3). Thus, if a drug lacks an "original NDA", it is subject to the lower, noninnovator formula—whether it has therapeutic equivalents or not. CMS said as much in February 2012, when it proposed to define "noninnovator multiple source drug" to include "any noninnovator drug that is not therapeutically equivalent". *See* 77 Fed. Reg. 5318, 5360 (Feb. 2, 2012); *see also*

that Mylan had to disclose that it was "knowingly misclassifying" EpiPen fails as a matter of law.[7]

Alleged Exclusive Dealing Regarding EpiPen for Schools (Compl. ¶¶ 101-03). Plaintiffs allege that Defendants failed to disclose their purportedly anticompetitive "exclusive dealing agreements with schools" for EpiPen. As an initial matter, Plaintiffs fail to plead any economic loss resulting from Defendants' alleged failure to disclose the supposed anticompetitive nature of these agreements. That is, the agreements are not alleged to have been the subject of any "bad news" disclosures that resulted in a drop in Mylan's stock price. For this reason alone, Plaintiffs' challenges relating to Mylan's contracts with schools must be dismissed.

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81 Fed. Reg. at 5198 (explaining that the decision not to adopt the proposed definition was "not designed to have any rebate implications"). Thus, once again, Plaintiffs' supposed "bright-line rule" conflicts with the statute and CMS' guidance, and cannot support the allegations of fraud.

[7] Plaintiffs make two related allegations that must also be dismissed. *First*, they allege that Mylan's disclosure of the general rebate rule—"13% [for] . . . products marketed under ANDAs" and 23% for "products marketed under NDAs" (Compl. ¶ 203)—was misleading because it did not disclose that Mylan was paying the lower (13%) rebate for EpiPen. (*See id.* ¶¶ 64, 203-04.) But this statement "must be considered in context", *Iowa Pub. Emps.' Ret. Sys. v. MF Glob., Ltd.*, 620 F.3d 137, 141 (2d Cir. 2010), including in light of Mylan's repeated, detailed risk disclosure that the relevant MDRP legal regime is "complex", "involve[s] . . . subjective decisions and complex methodologies", and is "subject to risk of errors", "review and challenge by the applicable governmental agencies", which could have "material adverse . . . consequences" for Mylan's business (2016 10-K (Ex. 4) at 43; 2013 10-K (Ex. 7) at 32; 2014 10-K (Ex. 6) at 35; 2015 10-K (Ex. 5) at 39). No reasonable investor would have understood Mylan's statement of the general rule as a representation that any particular Mylan product would necessarily be subject to a specific rebate.

Second, Plaintiffs allege that Mylan's cautionary statements concerning the complexity of the MDRP regime are false because the regime is, in fact, simple. (Compl. ¶¶ 205-06.) As is evident from even a cursory review of the relevant regulations (summarized above), the legal regime is extremely complex—and Mylan's risk disclosures were clearly true. Furthermore, "[c]autionary statements of potential risk have only rarely been found to be actionable by themselves". *FBR*, 544 F. Supp. 2d at 360, 362 (finding that risk disclosures about dangers of regulatory noncompliance were not actionable); *see also In re Noah Educ. Holdings, Ltd. Sec. Litig.*, No. 08 CIV. 9203 (RJS), 2010 WL 1372709, at *7 (S.D.N.Y. Mar. 31, 2010) (same). Clearly, they should not be so found here.

See Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005); *Ashland*, 652 F.3d at 337; *In re Manulife Fin. Corp. Sec. Litig.*, 276 F.R.D. 87, 103-04 (S.D.N.Y. 2011).

Moreover, Plaintiffs' conclusory allegations do not plead underlying misconduct requiring disclosure. Agreements of this kind are presumptively lawful, and Plaintiffs make no effort to allege that any supposed "anticompetitive effects outweigh [the] procompetitive effects" of these agreements, *E&L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29-30 (2d Cir. 2006), or that any competition allegedly foreclosed by such agreements "constitute[s] a substantial share of the relevant market" for a sufficient period of time, *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961), as required to state an antitrust claim under this theory.

Alleged "Pay-for-Delay" Regarding EpiPen (Compl. ¶¶ 93-100). Plaintiffs allege that Defendants failed to disclose an allegedly anticompetitive agreement involving Teva that "*likely* contained" a provision "to delay entry of a generic competitor to the EpiPen". (*Id.* ¶¶ 97, 245 (emphasis added).) Once again, Plaintiffs do not even attempt to demonstrate that this alleged agreement—to which Mylan is not even alleged to be a party—delayed entry by a generic competitor or violates antitrust law. To state an antitrust claim under a "reverse payment" theory, a plaintiff must, at a minimum, plead facts sufficient to show an actual "reverse payment" that is likely to "bring[] about anticompetitive effects", based on "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification". *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013). Plaintiffs fail to plead *any* of these factors. Again, Plaintiffs' conclusory allegations do not plead any underlying misconduct that had to be disclosed.

Alleged Market-Allocation of Doxycycline (Compl. ¶¶ 112-26). Plaintiffs assert that Defendants failed to disclose that they allegedly allocated markets for doxycycline with Heritage. However, Plaintiffs fail to allege any "direct or circumstantial evidence that reasonably tends to prove that [Mylan] and others had a conscious commitment" to allocate markets. *Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 519-20 (S.D.N.Y. 2013). While Plaintiffs refer to a number of alleged communications between Heritage and unspecified "Mylan executives" (Compl. ¶ 117), Plaintiffs make only conclusory allegations about the content of these alleged conversations—for example, that "Heritage and Mylan executives agreed to allocate the market for [doxycycline]", and that Heritage contacted Mylan "in an effort to discuss dividing the market for doxycycline" (*id.*). Conclusory allegations just like these, that companies agreed to allocate markets, have been rejected by the Supreme Court. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007) ("[A] conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality."). Plaintiffs' other allegations of market-allocation concern an alleged conspiracy between Heritage and *Mayne*—not Mylan. (*See* Compl. ¶¶ 120-26.) These allegations—concerning *another* company—do not plead *Mylan's* involvement in any scheme requiring disclosure.

Alleged Price-Fixing Regarding Other Generic Drugs (Compl. ¶¶ 127-87). Finally, Plaintiffs allege that Defendants failed to disclose that they supposedly engaged in price-fixing in connection with five other generic drugs. But Plaintiffs do not allege any direct evidence of a conspiracy. Instead, they point only to industry conferences purportedly attended by unspecified Mylan employees, and then to purported price increases many months later, asking this Court to infer a conspiracy. (*See id.* ¶¶ 127-84.) Plaintiffs repeat this same pattern nearly verbatim for each drug. (*See id.*) These allegations fail.

As a matter of law, allegations of parallel price increases—even "conscious parallelism"—are inadequate to establish an antitrust conspiracy. *Twombly*, 550 U.S. at 553-54, 556 n.4 (requiring allegations of parallel conduct that "would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties"). Such allegations may be "consistent with conspiracy, but [they are] just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market". *Id*.; *see also In re Zinc Antitrust Litig.*, 155 F. Supp. 3d 337, 366 (S.D.N.Y. 2016) ("By engaging in conscious parallelism, firms in a concentrated market may lawfully recognize shared economic interests and, in effect, lawfully exercise their leverage to set prices at a profit maximizing—and even a supra-competitive—level."). The alleged price increases here are entirely consistent with lawful price-following (or other benign explanations), and thus do not support any claim of price-fixing.[8] Furthermore, it is insufficient to allege that parallel price increases followed conferences attended by industry participants (Compl. ¶¶ 130, 136, 142, 148); *see Zinc*, 155 F. Supp. 3d at 366; Areeda & Hovenkamp, *Antitrust Law* ¶ 1433a (2d ed. 2003), or that Mylan operated in an oligopolistic market for the relevant drugs (Compl. ¶¶ 162-84); *see Mayor & City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 139 (2d Cir. 2013) (finding that allegations of

[8] Notably, several of the generics markets discussed by Plaintiffs do not even exhibit parallel price movements, according to Plaintiffs' own pleadings. Take divalproex: far from displaying a "one-way" price ratchet, the Complaint reveals erratic price movements in the market, with substantial price drops followed by increases and ultimately a return to earlier price levels. (*See* Compl. ¶ 149 Fig. D.) Competitors do not appear to be moving in sync—indeed, for lengthy periods of time competitors were charging significantly different prices, with new competitors entering the market at various price levels. (*Id*.) Similarly, far from price-fixing, the alleged price movements of benazepril and propranolol reveal lengthy periods, sometimes years, of inconsistent pricing by competitors, and at least in the case of benazepril, significant price drops following price hikes. (*See id.* ¶¶ 137 Fig. B, 155 Fig. E.) Even if parallel conduct were sufficient here—and it is not, *see Twombly*, 550 U.S. at 554—Plaintiffs fail to allege it.

oligopoly "simply restate the (legally insufficient) fact that market behavior is interdependent and characterized by conscious parallelism").[9] Plaintiffs' conclusory allegations fall short of pleading illegal price-fixing requiring disclosure.

* * *

Plaintiffs have failed to allege a single instance of underlying misconduct requiring disclosure. The portion of their Section 10(b) claim that relies on alleged wrongdoing by Mylan should be dismissed for this reason alone.

ii. Defendants Had No Duty To Disclose the Alleged, Unadjudicated Wrongdoing.

Even if Plaintiffs had adequately pleaded that Defendants knowingly misclassified EpiPen or engaged in anticompetitive conduct—and they did not—"the securities laws do not impose a general duty to disclose corporate mismanagement or uncharged criminal conduct". *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 403 (S.D.N.Y. 2016). It simply cannot be—and is not—the law that a company, for fear of violating the *securities* laws, is required to make binding public statements about uncharged misconduct in *other* areas before that conduct has ever been adjudicated. "[T]he federal securities laws do not require a company to accuse itself of wrongdoing." *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (collecting cases); *see also Menaldi*, 164 F. Supp. 3d at 582 ("Disclosure is not a rite of confession." (alterations and internal quotation marks omitted)).

All of the alleged misconduct on which Plaintiffs predicate their claims was uncharged and unadjudicated at the time Plaintiffs say disclosure was required—and remains so today.

[9] In any event, Plaintiffs' theory of meetings followed by price-hikes does not even work. For example, for both benazepril and divalproex, Plaintiffs allege that conspiracies to fix prices took place at meetings in February 2013 (Compl. ¶¶ 136, 148), and yet there were no contemporaneous price movements (*see id.* ¶¶ 137 Fig. B, 149 Fig. D). And for propranolol, Plaintiffs do not allege any price-fixing meetings at all.

Indeed, Plaintiffs do not allege that *any* court or agency has *ever* found that Mylan misclassified EpiPen (let alone knowingly) or that Mylan *ever* engaged in any of the supposedly anticompetitive acts Plaintiffs cobble together. Since there is no duty to disclose uncharged misconduct—even if such misconduct is sufficiently alleged (and it is not here (*see* Section I.A.i))—this portion of Plaintiffs' Section 10(b) claim fails for this independent reason too.[10]

B. Plaintiffs Have Not Sufficiently Alleged that Defendants Acted with Scienter.

To survive Defendants' motion to dismiss, Plaintiffs must plead "with particularity", and "with respect to each act or omission alleged to violate" the securities laws, "facts giving rise to a strong inference" of scienter, 15 U.S.C. § 78u-4(b)(2)(A)—that is, a strong inference that Defendants acted with an "intent to deceive, manipulate or defraud" investors, or that Defendants acted recklessly, *i.e.*, in "an extreme departure from the standards of ordinary care", *Kalnit v. Eichler*, 264 F.3d 131, 138, 142 (2d Cir. 2001). Under this standard, the inference of scienter "must be more than merely 'reasonable' or 'permissible'—it must be . . . cogent and at least as compelling as any opposing inference one could draw from the facts alleged". *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). What are required are "facts . . . showing that the [D]efendants had both motive and opportunity to commit the fraud", or

[10] While Plaintiffs challenge a number of Mylan's disclosures about its revenues—not as inaccurate but because they were not accompanied by groundless statements of self-flagellation—accurate disclosures of past financial performance are inactionable and do not trigger a duty to disclose uncharged alleged misconduct. *See Nadoff v. Duane Reade, Inc.*, 107 F. App'x 250, 252 (2d Cir. 2004) ("Accurate statements about past performance are self-evidently not actionable under the securities laws . . . ."); *FBR*, 544 F. Supp. 2d at 356 (same); *In re Marsh & Mclennan Cos., Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 470 (S.D.N.Y. 2006) ("[T]he allegation that a corporation properly reported income that is alleged to have been, in part, improperly obtained is insufficient to impose Section 10(b) liability."); *Citigroup*, 330 F. Supp. 2d at 377 ("Plaintiff's allegation that Citigroup's failure to disclose that its revenues were derived from 'unsustainable and illegitimate sources' violated section 10(b) is . . . unavailing, for the federal securities laws do not require a company to accuse itself of wrongdoing.").

"constituting strong circumstantial evidence of conscious misbehavior or recklessness". *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 384 (S.D.N.Y. 2007).

Plaintiffs do not make a single allegation of motive with respect to any Defendant. Instead, Plaintiffs rely on a mishmash of thin, circumstantial claims, throwing every possible scienter theory at the wall to see what sticks. (*See* Compl. ¶¶ 325-38.) But absent evidence of motive, "the strength of the[se] circumstantial allegations [of scienter] must be correspondingly greater". *Kalnit*, 264 F.3d at 142. As explained below, however, *none* of Plaintiffs' scienter allegations—either independently or together—gives rise to a compelling inference of scienter. This is particularly clear in light of: (i) CMS' longstanding advice that EpiPen was *properly* classified as a noninnovator; (ii) the fact that CMS has stated that the controlling statutory definition is ambiguous and has propounded a rule under which that definition must be applied on a case-by-case basis in light of the unique facts and circumstances of each product; (iii) the conclusory and speculative allegations by Plaintiffs of any antitrust violations; and (iv) the fact that no court or other authority has ever found that Mylan committed *any* of the alleged misconduct.

The more "cogent" and "compelling" inference, *Tellabs*, 551 U.S. at 324, is not that Defendants acted with intent to mislead when they did not confess to regulatory or antitrust wrongdoing, and when they did not immediately announce an investigation into Mylan's (and its predecessor's) longstanding, government-approved treatment of EpiPen. The more compelling inference is that Defendants acted within the law and consistent with the facts at all relevant times.

i. Individual Defendants' Positions at Mylan

Plaintiffs allege that the Individual Defendants, "by virtue of their responsibilities and activities" as Mylan executives or directors, "were privy to[] and participated in the fraudulent

conduct described in this Complaint". (Compl. ¶ 326.) But "[c]ourts in this Circuit have long held that accusations founded on nothing more than a defendant's corporate position are entitled to no weight." *Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Commerce*, 694 F. Supp. 2d 287, 300 (S.D.N.Y. 2010); *see also Mechel*, 811 F. Supp. 2d at 873 ("[T]hese position-based allegations are substantively indistinguishable from those routinely held insufficient to plead scienter."). Moreover, the PSLRA requires Plaintiffs to plead scienter "with respect to *each act or omission* alleged to" be misleading. 15 U.S.C. § 78u-4(b)(2) (emphasis added). Obviously, a blanket pleading such as this—that the Individual Defendants' positions made them knowledgeable of *all* "the fraudulent conduct described" (Compl. ¶ 326)—fails to meet the PSLRA's particularity requirement.

ii. EpiPen's Importance to Mylan's Business

Plaintiffs allege that, because EpiPen is "part of Mylan's core business", the Individual Defendants would have to have known that Mylan's revenue and income statements were inflated by the purported misclassification of EpiPen and by alleged anticompetitive conduct relating to that drug. (Compl. ¶ 327.) But courts in this District have repeatedly called into question the viability of "core operations" allegations such as these following enactment of the PSLRA. *See, e.g.*, *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 596 n.17 (S.D.N.Y. 2011) ("It is questionable whether the 'core operations' doctrine has survived the PSLRA at all."); *Plumbers & Pipefitters Local Union No. 630 Pension-Annuity Tr. Fund v. Arbitron Inc.*, 741 F. Supp. 2d 474, 490 (S.D.N.Y. 2010) ("Those Courts of Appeals that have addressed the question have found that [the 'core operations' doctrine] is no longer viable in most situations."). Even if the doctrine were viable, Plaintiffs' allegations are ineffective in the absence of other allegations independently establishing scienter, which Plaintiffs have failed to make. *See Total Equity Capital, LLC v. Flurry, Inc.*, No. 15-CV-4168 (JMF), 2016 WL 3093993, at *5 (S.D.N.Y.

June 1, 2016) ("[E]ven if the doctrine does remain valid, core operations allegations would constitute supplementary but not independently sufficient means to plead scienter." (internal quotation marks omitted)); *Mechel*, 811 F. Supp. 2d at 873 (holding that giving credence to "core operations" allegations, absent other, compelling facts, "would eviscerate the cogent and compelling inference of scienter required by *Tellabs*").

iii. SOX Certifications

Plaintiffs conclusorily allege that the SOX certifications signed by the Individual Defendants attest to their knowledge that certain statements made in Mylan's filings were misleading. (*See, e.g.*, Compl. ¶ 328.) But again, without other allegations independently sufficient to establish scienter, Plaintiffs "cannot raise an inference of fraudulent intent based on the signing of a certification", *Plumbers & Pipefitters Nat'l Pension Fund v. Orthofix Int'l N.V.*, 89 F. Supp. 3d 602, 615 (S.D.N.Y. 2015), and certainly cannot do so without "offer[ing] any particularized allegation of an inference that . . . the . . . certifications . . . were not honestly and reasonably believed to be true when made", *In re Turquoise Hill Res. Ltd. Sec. Litig.*, No. 13 CIV. 8846 LGS, 2014 WL 7176187, at *7 (S.D.N.Y. Dec. 16, 2014).

iv. Government Investigations

Plaintiffs allege that the Individual Defendants knew that certain statements concerning revenue and the MDRP were misleading because CMS had informed Mylan of its view that EpiPen was misclassified, and because the DOJ had opened an investigation to that effect. (Compl. ¶¶ 331, 334.) Similarly, Plaintiffs allege that the Individual Defendants knew that statements about competition in generics markets and statements about Mylan's income and revenue were misleading because certain government antitrust investigations had been commenced. (*Id.* ¶ 334.) But "knowledge of the existence of an investigation is not sufficient to support an inference of scienter". *Youngers v. Virtus Inv. Partners Inc.*, 195 F. Supp. 3d 499,

517 (S.D.N.Y. 2016); *see also Lipow v. Net1 UEPS Techs., Inc.*, 131 F. Supp. 3d 144, 167 (S.D.N.Y. 2015) ("[G]overnment investigations cannot bolster allegations of scienter that do not exist, and, as currently pled, the government investigations are just that, investigations."). The mere fact of a government agency investigating compliance by a public company like Mylan cannot evince scienter. *See Manulife*, 276 F.R.D. at 102 ("Securities regulators are obligated to examine the behavior of public corporations, and the fact that a regulator is fulfilling this role cannot be sufficient to allege scienter."). As Plaintiffs acknowledge, an investigation does not imply that the conduct being investigated actually occurred. (*See, e.g.*, Compl. ¶¶ 99, 331.) With respect to EpiPen's classification after all, Mylan was simply complying with longstanding guidance from CMS. Clearly, Defendants were not motivated by any desire to mislead investors.

v. Settlement of the DOJ Investigation

Plaintiffs allege that scienter regarding statements concerning EpiPen's classification can be inferred from Mylan's settlement of the DOJ Investigation. (Compl. ¶ 335.) But this allegation also does not establish scienter, because settlement agreements do not prove scienter. *See In re DNTW Chartered Accountants Sec. Litig.*, 172 F. Supp. 3d 675, 690 (S.D.N.Y. 2016) (settlement agreements with the SEC are "not sufficient to meet [scienter] pleading requirements" (quoting *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 748 (9th Cir. 2008))), *aff'd*, 666 F. App'x 78 (2d Cir. 2016); *see also* Fed. R. Evid. 408(a) (explicitly prohibiting the use of evidence of settlement to prove the "validity . . . of a disputed claim"). Plaintiffs appear to suggest that the fact of entering into a settlement with the DOJ implies wrongdoing, thus suggesting scienter. But of course, there are many reasons why a company would enter into a settlement—including agreeing to a sizeable monetary payment—even if it did not commit the alleged wrongdoing. Mylan said as much in its press release announcing the

settlement, in which it made clear that it had classified EpiPen in a manner consistent with guidance from CMS, and that it was admitting no wrongdoing. (2016 8-K (Ex. 2) at 2.)

vi. Alleged Involvement in Pricing

Relying on the allegations of a so-called "confidential witness", Plaintiffs allege that the Individual Defendants "each knew of and approved all material pricing decisions made by the Company". (Compl. ¶¶ 109-11, 332-33.) But the confidential witness says nothing at all about EpiPen's classification or Plaintiffs' allegations of anticompetitive conduct with respect to EpiPen. And with respect to supposed market-allocation and price-fixing, the confidential witness does not even try to claim that any Individual Defendant was aware of any agreement at all regarding any drug. Still less does the confidential witness "establish what specific . . . information [contradicting Mylan's disclosures] the Individual Defendants received or when they received it". *Local No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Express Co.*, 724 F. Supp. 2d 447, 461 (S.D.N.Y. 2010), *aff'd*, 430 F. App'x 63 (2d Cir. 2011). The confidential witness also says nothing about having had any contact with any of the Individual Defendants, so as to have personal knowledge of their state of mind when they spoke—which, of course, is what matters for scienter. *See Glaser*, 772 F. Supp. 2d at 595 (discounting confidential witness' allegations of scienter because of no indication that the witness had any contact with any individual defendant); *Am. Express*, 724 F. Supp. 2d at 460-62 (same). At best, the confidential witness suggests, unremarkably, that certain Mylan executives may have been involved in some fashion in "material pricing decisions made by the Company". (Compl. ¶ 332.)[11] Alleging general involvement in certain internal pricing decisions comes nowhere close to alleging that

[11] Curiously, the confidential witness claims to have personal knowledge of Defendant Parks' involvement in pricing issues (*id.* ¶¶ 110, 332), even though Parks joined the Company nine months after the confidential witness departed it (*id.* ¶ 31).

the Individual Defendants had any knowledge of alleged price-fixing, market-allocation or other anticompetitive activity, and of course has nothing to do with EpiPen's MDRP classification.

vii. Price Movements

For their final theory, Plaintiffs allege that scienter can be inferred from certain purported drug price increases "immediately following [certain industry] meetings". (*Id.* ¶ 338.) Plaintiffs appear to allege simply that the Individual Defendants should have known that anticompetitive activity was supposedly taking place because of the timing of these alleged price increases. This is insufficient to raise a "strong inference" of scienter, however, since rising prices are consistent with innocent business activities. (*See* Section I.A.i.) Moreover, even if Plaintiffs had sufficiently alleged price-fixing by Mylan—and they have not come close to doing so (*see id.*)—the mere fact of rising prices certainly does not demonstrate that any of the Individual Defendants knew that Mylan was engaged in such activity. While Plaintiffs allege, "on information and belief", that all Individual Defendants were aware of each of the five purported price-fixing conspiracies (Compl. ¶¶ 128, 134, 140, 146, 152), Plaintiffs allege no facts at all (no comments, no documents, nothing) to support these claims—and thus fail to "state with particularity all facts on which that belief is formed", 15 U.S.C. § 78u-4(b)(1); *see also Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). Conclusory allegations such as these do not establish scienter.

* * *

Plaintiffs have failed to plead any cogent or compelling inference of scienter—the more compelling inference being that Defendants were doing their best simply to comply with the law. This is a further independent reason to dismiss Plaintiffs' Section 10(b) claim (Count I).

C. Plaintiffs' Loss Causation Allegations Are Deficient.

Even if Plaintiffs had sufficiently pleaded falsity and scienter—and they have not (*see* Sections I.A and I.B)—nearly 85% of Plaintiffs' claimed losses would still have to be dismissed because, among other reasons, they were not caused by anything that Defendants are claimed to have misrepresented. *See, e.g.*, *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005) ("[T]o establish loss causation, a plaintiff must allege that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." (alterations, citation, emphasis and internal quotation marks omitted)); *Leykin v. AT&T Corp.*, 423 F. Supp. 2d 229, 245 (S.D.N.Y. 2006) (revelation of bad news unrelated to underlying alleged fraud is insufficient to plead loss causation); *GE Inv'rs v. Gen. Elec. Co.*, 447 F. App'x 229, 232 (2d Cir. 2011) (same); *see also Broudo*, 544 U.S. at 345 ("[The securities] statutes . . . [exist] not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.").

First, a number of Plaintiffs' loss allegations concern the disclosure of "bad news" that had nothing to do with any alleged misrepresentation by Defendants. Most significantly, Plaintiffs allege that they suffered a loss of $6.17 per share between August 19 and August 24, 2016, when certain news articles and other information were published "highlighting the price increases in the EpiPen over the prior years". (Compl. ¶¶ 302-07.) But the possibility or fact of EpiPen price increases is not something Defendants are alleged to have concealed. Similarly, Plaintiffs allege that they suffered a loss of $1.24 per share on October 12, 2016, when a news article reported that the true cost to Mylan of the DOJ settlement (which had already been

disclosed) may be greater than $465 million. (*Id.* ¶¶ 313-14.) But the settlement cost is not something Defendants allegedly misrepresented. Plaintiffs cannot recover for these losses.

Second, certain other losses alleged by Plaintiffs must also be dismissed, because they concern the disclosure of "bad news" that was already public. *See In re CRM Holdings, Ltd. Sec. Litig.*, No. 10 Civ. 975 RPP, 2012 WL 1646888, at *31 (S.D.N.Y. May 10, 2012) ("[Plaintiffs] cannot establish loss causation merely by relying on an after-the-fact negative characterization of already-public information." (internal quotation marks omitted)). For example, news articles on October 5 and October 7, 2016 discussing the alleged misclassification of EpiPen (Compl. ¶¶ 309-12) simply repeated news already revealed a month earlier, on September 2 (*id.* ¶¶ 308-09). Yet Plaintiffs try to plead a loss of $2.09 per share based on that old news.[12] Plaintiffs likewise allege a loss of $3.17 per share based on news articles from November 3 and November 10, 2016 that discussed the DOJ's antitrust investigation (Compl. ¶¶ 315-18), which had been disclosed months earlier (*see* 2016 10-K at 160). Finally, the plea deals reported on January 10, 2017 (Compl. ¶¶ 321-22)—on which Plaintiffs claim $2.18 per share in loss—were publicized almost a month earlier, on December 14, 2016 (*id.* ¶ 319). Since the "news" provided on each of these dates was already public, the substantial drops in Mylan's stock price that are alleged to have accompanied them are not actionable, and must be dismissed. *See CRM*, 2012 WL 1646888, at *31.

In light of Plaintiffs' failure to plead loss causation, if the Court does not dismiss the Complaint in its entirety, it should at the very least dismiss Plaintiffs' alleged losses from

[12] Falsely, Plaintiffs allege that Mylan's stock price fell on October 7, 2016 on news of the Company's settlement with the DOJ. (*See id.* ¶¶ 311-12.) In fact, Mylan announced the settlement *after* the close of trading on October 7; the stock opened up more than 12% the next trading day. *See Miller v. Lazard, Ltd.*, 473 F. Supp. 2d 571, 578 (S.D.N.Y. 2007) ("[T]he court may take judicial notice of well-publicized stock prices without converting the motion to dismiss into a motion for summary judgment." (internal quotation marks omitted)).

August 19 through August 24, 2016, on October 5, October 7, October 12, November 3 and November 10, 2016, and on January 10, 2017—which account for nearly $15 in alleged per-share losses, or nearly 85% of Plaintiffs' total claim.

II. PLAINTIFFS FAIL TO STATE A CLAIM FOR VIOLATION OF SECTION 20(a).

Because Plaintiffs fail to state a claim for a primary violation under Section 10(b), their Section 20(a) claim (Count II) must also be dismissed. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

III. PLAINTIFFS FAIL TO STATE A CLAIM FOR VIOLATION OF ISRAELI LAW.

Plaintiffs' Israeli law claim must be dismissed for reasons of both substance (*see* Section III.A) and procedure (*see* Section III.B). Each is sufficient to require dismissal.

A. Plaintiffs Fail To Allege Any Violation of Israeli Law.

Plaintiffs allege that their claim under Israeli law is predicated on the alleged violation of Section 10(b). (*See* Compl. ¶¶ 366-68.) However, Plaintiffs have failed to plead a violation of Section 10(b). (*See* Section I.) Alternatively, Plaintiffs try to allege that Defendants independently breached various provisions of Israeli securities and torts laws. (Compl. ¶ 369.) But these alternative pleadings include little more than a recitation of the language of the provisions; they fail to plead the elements of any such claim, let alone facts tending to show the elements are met. *See Twombly*, 550 U.S. at 570. Either way, Plaintiffs fail to plead a violation of Israeli law, and their Israeli law claim should be dismissed.

B. The Court Should Dismiss the Israeli Law Claim on Grounds of Jurisdiction and Convenience.

Plaintiffs' Israeli law claim is also afflicted by three independent defects of jurisdiction and forum, each of which warrants dismissal of the claim.

First, this Court lacks personal jurisdiction over Defendants with respect to the Israeli law claim. Neither Mylan N.V. nor Mylan Inc. is a resident of New York—the former is a Dutch corporation, the latter is a Pennsylvania corporation and both have their principal places of business outside of New York. (*See* Compl. ¶¶ 26-27.) And Plaintiffs make no allegations at all about the domiciles of the Individual Defendants. (*See id.* ¶¶ 28-32.) Absent affiliations with New York "so continuous and systematic as to render [Defendants] essentially at home in the forum", *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014) (internal quotation marks omitted), there is no general jurisdiction over Defendants. Nor is there specific jurisdiction, as the Israeli law claim—which arises out of purchases by the corporate Plaintiffs (all Israeli investment firms) of Mylan N.V. stock on the Israeli TASE—has no connection to New York, nor have Plaintiffs alleged any. (*See* Compl. ¶¶ 363-69); *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 624 (2d Cir. 2016). The Israeli law claim should be dismissed for lack of personal jurisdiction. *See* Fed. R. Civ. P. 12(b)(2).

Second, the Court should decline to exercise supplemental jurisdiction over the Israeli law claim once the U.S. claims are dismissed, as in that circumstance, there would be no claims over which this Court has original jurisdiction. *See Wallert v. Atlan*, 141 F. Supp. 3d 258, 278 (S.D.N.Y. 2015). Even if the Court does not dismiss the U.S. claims, the Court should still decline to exercise supplemental jurisdiction over the Israeli law claim because adjudicating that claim would require the application of foreign law to a claim for purchases by foreign entities on a foreign stock exchange. Courts have routinely declined supplemental jurisdiction in similar circumstances. *See Roman Y Gordillo, S.C. v. Bank of N.Y. Mellon Corp.*, No. 12-cv-0212 (DF), 2014 WL 3507300, at *11-12 (S.D.N.Y. July 14, 2014) (refusing to exercise supplemental jurisdiction where the court would "need to apply Mexican law to determine the validity of an

agreement allegedly formed in Mexico between two Mexican parties"); *In re Toyota Motor Corp. Sec. Litig.*, No. CV 10-922 DSF (AJWx), 2011 WL 2675395, at *7 (C.D. Cal. July 7, 2011) (refusing to allow Japanese securities law claims to "piggyback[]" onto a Rule 10b-5 action); *Dar El-Bina Eng'g & Contracting Co. v. Republic of Iraq*, 79 F. Supp. 2d 374, 387-88 (S.D.N.Y. 2000) ("The United States has little if any interest in providing a forum for the resolution of those [foreign] aspects of this case . . . . The parties to the guarantees and the notes all are foreign. The obligations are denominated in foreign currencies. The place(s) for performance were abroad."); Fed. R. Civ. P. 12(b)(1). Indeed, Plaintiffs' Israeli law claim asks this Court to exercise jurisdiction over issues that are one step further removed from U.S. interests than even "foreign-cubed" securities claims, which the Supreme Court has deemed outside the extraterritorial reach of U.S. courts. *See Morrison v. Nat'l Austl. Bank Ltd.*, 561 U.S. 247, 273, 283 n.11 (2010). Here, like in *Morrison*, *foreign* investors are suing a *foreign* issuer for losses on a *foreign* exchange. But unlike in *Morrison*, where the "foreign-cubed" claims were at least brought under U.S. securities laws, Plaintiffs here are seeking to apply only *foreign* law to the foreign trades. The Israeli law claim should be dismissed.

Third, this Court should dismiss the Israeli law claim under the doctrine of *forum non conveniens*, which "permits a court to resist imposition upon its jurisdiction even when jurisdiction is authorized by the letter of a general venue statute, if dismissal would best serve the convenience of the parties and the ends of justice". *Murray v. British Broad. Corp.*, 81 F.3d 287, 290 (2d Cir. 1996) (internal quotation marks and citation omitted). Here, the ends of justice would best be served by dismissing the Israeli law claim in favor of Israel, where nearly identical

securities claims have been asserted against Mylan and each of the Individual Defendants.[13] *See USHA (India), Ltd. v. Honeywell Int'l, Inc.*, 421 F.3d 129, 134 (2d Cir. 2005). Furthermore, Plaintiffs' choice of forum should be accorded no deference: the so-called "Israeli Investor Group" of Plaintiffs brings this claim under Israeli law, in connection with the stock of a Dutch corporation, purchased on an Israeli stock exchange; there is little connection to the U.S. *See Iragorri v. United Techs. Corp.*, 274 F.3d 65, 72 (2d Cir. 2001). And the public and private interest factors also favor adjudication of the Israeli law claim in Israel: in addition to the obvious interest in having a claim under Israeli law, brought by Israeli investors, regarding stock on an Israeli exchange, decided by an Israeli court, Defendants face the prospect of double exposure if the Israeli law claim is litigated in the U.S., since it is unclear whether a judgment concerning the TASE class here would be recognized by the Israeli courts. *See* Accompanying Declaration of Adv. Zvi Agmon (analyzing Israeli law on this question); CA 3973/10 *Stern v. VeriFone Holdings, Inc.* [2015] (Isr.) (Ex. 8); *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508 (1947); *Wallert*, 141 F. Supp. 3d at 279-82; *Stewart v. Adidas A.G.*, No. 96 Civ. 6670 (DLC), 1997 WL 218431, at *7 (S.D.N.Y. Apr. 30, 1997) ("[I]t is not clear that German courts would even recognize an American judgment based on German copyright law."); Fed. R. Civ. P. 44.1.

In all events, the Israeli law claim (Count III) should be dismissed.

CONCLUSION

For these reasons, the Complaint should be dismissed in its entirety, and with prejudice.

[13] *See* CC (TA) 50981/04 *Mgmt. Co. of the Continuing Educ. Fund for Emps. of the Isr. Elec. Corp. v. Mylan N.V., et al.* [2017] (Isr.) (Ex. 10) (filed Apr. 30, 2017); CC (TA) 18217/10 *Friedman v. Mylan N.V., et al.* [2016] (Isr.) (Ex. 9) (filed Oct. 13, 2016, and stayed since Jan. 19, 2017, pending resolution of the present case). To be clear, Defendants have a number of procedural and substantive defenses to these pending Israeli claims—but clearly the defenses are most appropriately asserted in Israel, rather than here.

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Respectfully submitted,

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